Rejections under 35 U.S.C. § 112, 2nd ¶

The Examiner rejected Claims 13-15 and 17 because of informalities. Claims 13, 14 and 17 have been amended to provide for proper claim dependencies. Applicant respectfully requests the Examiner to withdraw the rejection and to pass Claims 13-15 and 17 to allowance.

Rejections under 35 U.S.C. § 102(b)

Applicant submits that the subject matter of independent Claims 1, 12 and 16 is patentably distinguished over the references cited by the Examiner. For example, as to Claim 1, the references fail to disclose or suggest a processor having a plethysmograph waveform input, which results from light attenuated by body tissue with pulsing blood, and a pulse recognition output providing information regarding pulses within the waveform input, wherein a candidate pulse portion determines a plurality of potential pulses within the waveform input, and wherein a physiological model portion determines the physiologically acceptable ones of the pulses. For example, instead of generating and processing a plethysmograph waveform input resulting from light attenuated by body tissue with pulsing blood, two references (Kaspari, Bernard) teach to use pressure sensors that generate pulse signals from a body part, and two references (Bernard, Leon) fail to disclose a plethysmograph waveform at all.

Rejections over Kaspari

The Examiner rejected independent Claims 1 and 12 as being anticipated by Kaspari (U.S. Patent No. 4,295,471). Further, the Examiner rejected dependent Claims 2, 3, 5-7, 11 and 13-15 as being anticipated by Kaspari. For the reasons set forth hereinafter, Applicant submits that Claims 1-3, 5-7 and 10-15 contain limitations that are not disclosed or suggested by Kaspari. Applicant therefore respectfully submits that Claims 1-3, 5-7 and 10-15 are not anticipated by Kaspari under 35 U.S.C. § 102(b).

As to independent Claims 1 and 12, the Examiner asserted that Kaspari discloses a processor and describes a process where signals generated by a transducer are converted to digital signals and stored for analysis (col. 2, lines 35-59). Further, the Examiner asserted that various techniques are utilized during analysis to ensure the validity of the data and to eliminate artifacts. The Examiner asserted also that Kaspari teaches waveforms that are heartbeats which comprise a plurality of pulses (col. 5, line 41-col. 6, line 45), and that Kaspari discloses the

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method of validating data and eliminating artifacts (col. 8, line 21 – col. 11, line 25). As discussed below, the portions of Kaspari to which the Examiner cites to do not disclose or suggest each and every element of Claims 1 and 12.

In particular, Kaspari does not disclose a processor or a method that process a plethysmograph waveform input resulting from light attenuated by body tissue with pulsing blood. Instead of light, Kaspari teaches to use piezoelectric elements in a pressure sensitive element. Pressure exerted on the piezoelectric elements is converted into electrical signals. Kaspari's pressure element provides no suggestion for a sensor that generates a plethysmograph waveform input resulting from light attenuated by body tissue with pulsing blood.

Further, Kaspari's piezoelectric elements generate two signals 6b, 6c which represent a series of pulses. The signal 6c is subtracted from the signal 6b to generate a differential signal 6d that may be integrated to generate the signal 6e (col. 5, lines 46-53). Thus, instead of generating a single signal, i.e., a plethysmograph waveform input resulting from light attenuated by body tissue with pulsing blood, Kaspari teaches to generate two signals, subtract the two signals from each other, and process the resulting signal.

Furthermore, Kaspari does not disclose a processor or a method in which a candidate pulse portion determines a plurality of potential pulses within the waveform input as defined in Claims 1 and 12 as amended. Kaspari's analog amplifiers 214 provide a differential output, i.e., the signal 6d, of the signals 6b and 6c (col. 7, lines 57-61 and Figure 3). After generating the signal 6d, Kaspari teaches a data accumulation procedure that compares the pulses to a noise threshold value to determine valid pulses, which are stored (col. 8, lines 29-44). A data analysis procedure sets an arbitrary time window and analyzes the amplitudes and polarities of the stored data (col. 10, lines 19-57). As Kaspari processes the differential signal 6d, Kaspari's method does not include determining a plurality of potential pulses within the waveform input as defined in Claims 1 and 12 as amended.

In view of these arguments, Applicant respectfully submits that independent Claims 1 and 12 as amended each include limitations that are not disclosed or suggested by Kaspari. Applicant respectfully submits that Claims 1 and 12 as amended are patentably distinguished over Kaspari. Applicant respectfully request the Examiner to withdraw the rejection over Kaspari and to pass Claims 1 and 12 as amended to allowance.

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Claims 2, 3, 5-7, 11 and 13-15 depend directly or indirectly from Claims 1 and 12 as amended, respectively, and further define the invention defined in Claims 1 and 12, respectively. Thus, because of the reasons set forth above and because of the additional inventive features recited in the dependent claims, Applicant respectfully submits that Claims 2, 3, 5-7, 11 and 13-15 are patentably distinguished over Kaspari. Applicant respectfully requests the Examiner to withdraw the rejection of Claims 2, 3, 5-7, 11 and 13-15 and to pass Claims 2, 3, 5-7, 11 and 13-15 to allowance.

Rejections over Bernard

The Examiner rejected independent Claims 1, 12 and 16 as being anticipated by Bernard (U.S. Patent No. 5,274,548). Further, the Examiner rejected dependent Claims 4-7, 9-11 and 17 as being anticipated by Bernard. For the reasons set forth hereinafter, Applicants submits that Claims 1, 4-7, 9-12 and 16-17 contain limitations that are not disclosed or suggested by Bernard. Applicant therefore respectfully submits that Claims 1, 4-7, 9-12 and 16-17 are not anticipated by Bernard under 35 U.S.C. § 102(b).

As to independent Claims 1, 12 and 16, the Examiner asserted that Bernard discloses a method and apparatus for segmenting and classifying pulsed signals in medical applications (col. 2, lines 6-23), wherein the method may be applied to a noised pulse signal (col. 1, lines 13-17). Further, the Examiner asserted that Bernard teaches that heartbeats can be segmented in the method (col. 4, lines 13-17) and that Figure 2 shows a portion of a recorded pulse with multiple pulses. As discussed below, the portions of Bernard to which the Examiner cites to do not disclose or suggest each and every element of Claims 1, 12 and 16.

In particular, Bernard does not disclose a processor or a method that process a plethysmograph waveform input as defined in Claim 16 or a plethysmograph waveform input resulting from light attenuated by body tissue with pulsing blood as defined in Claims 1 and 12. As described at page 2, lines 5-7, and shown in Figures 1 and 3 of the present application, a plethysmograph waveform is a display of blood volume over time. In contrast, Bernard discloses that the disclosed method may be applied generally to a noised pulse signal (col. 1, lines 13-17). Thus, Bernard does not disclose a plethysmograph waveform input and no plethysmograph waveform input resulting from light attenuated by body tissue with pulsing blood.

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Bernard discloses an apparatus and method that are based on a different concept than the subject matter of Claims 1, 12, 16. Because of the different concept, Bernard fails to disclose a processor or a method in which a candidate pulse portion determines a plurality of potential pulses within the plethysmograph waveform. Instead, Bernard discloses a method for analyzing signals by means of segmentation and classification. Neither the segmentation nor the classification involve determining a plurality of potential pulses of a plethysmograph waveform input as defined in Claims 1, 12 and 16.

As to Claim 16, Bernard's segmentation is an iterative procedure in which arbitrary thresholds are set to merge neighboring pulses (col. 2, lines 23-31). As shown in Figure 2, the thresholds (amplitudes A_i) are varied until two pulses merge into a single pulse (col. 3, lines 33-41). Figure 2, line 2, shows a merged single pulse, and line f shows a series of segments each defining a pulse with a peak sample, a start sample and an end sample. The series of segments, however, does not represent a plurality of potential pulses identified as a triangular waveform. Thus, Applicant submits that independent Claim 16 includes a limitation that is not disclosed by Bernard.

The classification separates significant pulses from noise due to breathing, heartbeats and coughing of the patient (col. 4, lines 13-17). Note that Bernard considers heartbeats as noise, which is a further indication that Bernard does not disclose or suggest a plethysmograph waveform input. To classify the pulses, Bernard teaches to apply a statistical analysis according to the dynamic storm clouds method (col. 4, lines 18-19). Bernard's classification method is applied to the series of segments. Thus, Bernard fails to disclose or suggest an apparatus and method in which a physiological model is applied to determine physiologically acceptable pulses of the potential pulses identified by a triangular wave.

As to Claims 1 and 12, Bernard fails to disclose or suggest a processor or a method that process a plethysmograph waveform input resulting from <u>light</u> attenuated by body tissue with pulsing blood. Instead of light, Bernard teaches to use a <u>pressure sensor</u> (probe 74) located in a patient's esophagus (col. 5, lines 30-32). Pressure exerted on the pressure sensor during swallowing is converted into an electrical signal. Bernard's pressure sensor provides no suggestion for a sensor that generates a plethysmograph waveform input resulting from <u>light</u> attenuated by body tissue with pulsing blood.

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Thus, Applicant submits that independent Claims 1, 12 and 16 each include limitations that are not disclosed or suggested by Bernard. Applicant respectfully submits that Claims 1, 12, and 16 are patentably distinguished over Bernard. Applicant respectfully request the Examiner to withdraw the rejection of Claims 1, 12 and 16 and to pass Claims 1, 12 and 16 to allowance.

Claims 4-7, 9-11 and 17 depend directly or indirectly from Claims 1, 12 and 16, respectively, and further define the invention defined in Claims 1, 12 and 16, respectively. Thus, for the reasons set forth above and because of the additional inventive features recited in the dependent claims, Applicant respectfully submits that Claims 4-7, 9-11 and 17 are patentably distinguished over Bernard. Applicant respectfully requests the Examiner to withdraw the rejection of Claims 4-7, 9-11 and 17 and to pass Claims 4-7, 9-11 and 17 to allowance.

Rejections over Leon

The Examiner rejected independent Claims 1 and 12 as being anticipated by Leon (U.S. Patent No. 5,365,934). Further, the Examiner rejected dependent Claims 5-10, 13 and 15 as being anticipated by Leon. For the reasons set forth hereinafter, Applicant submits that Claims 1, 5-10, 12-12 and 15 contain limitations that are not disclosed or suggested by Leon. Applicant therefore respectfully submits that Claims 1, 5-10, 12, 13 and 15 are not anticipated by Leon under 35 U.S.C. § 102(b).

As to independent Claims 1 and 12, the Examiner asserted that Leon discloses a method and apparatus for measuring the heart rate using an autocorrelator that periodically generates an autocorrelation signal of the input signal over a predetermined time period (col. 2, lines 3-24). The Examiner asserted that the signal indication logic detects a periodic signal in the autocorrelation signal and generates a heart rate signal, and that, when using stair climbers and treadmills, it is difficult to isolate the user's heart rate (col. 14, line 31 – col. 15, line 17). Further, the Examiner asserted that a digital signal processor filters the autocorrelation output for the indications of periodic signals to reduce the autocorrelation signal to a plurality of candidate signals. The candidate signals are stored and sorted in descending order of frequency. The Examiner asserted also that the digital signal processor performs an arbitration function to select one of the candidate heart rate signals. As discussed below, the portions of Leon to which the Examiner cites to do not disclose or suggest each and every element of Claims 1 and 12.

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More particularly, Leon does not disclose a processor or a method that process a plethysmograph waveform input resulting from light attenuated by body tissue with pulsing blood as described at page 2, lines 5-7, and shown in Figures 1 and 3 of the present application. In contrast, Leon discloses that sensors at the handle of an exercise device detect a very low amplitude electrical signal generated by the body and known as a biopotential signal (col. 1, lines 21-23). Leon uses this body-generated biopotential signal to measure the heart rate (col. 2, lines 3-5). That is, Leon measures the heart rate from an electrical signal generated by the heart's periodic activity. A plethysmograph, however, represent the blood volume over time resulting from light attenuated by body tissue with pulsing blood. Thus, Leon does not disclose a plethysmograph waveform as an input. For that reason alone, Applicant submits that independent Claims 1 and 12 each include a limitation that is not disclosed by Leon.

Further, Leon fails to disclose a processor or a method in which a candidate pulse portion determines a plurality of potential pulses within the plethysmograph waveform. Instead, as confirmed by the Examiner, Leon autocorrelates the biopotential signal to generate a candidate signal.

As a consequence of Leon's failure to disclose or suggest a plethysmograph waveform input and a candidate pulse portion as defined in Claims 1 and 12, Applicant respectfully submits that Claims 1 and 12 each include additional limitations that are not disclosed or suggested by Leon. Applicant respectfully request the Examiner to withdraw the rejection of Claims 1 and 12 and to pass Claim 1 and 12 to allowance.

Claims 5-10, 13 and 15 depend directly or indirectly from Claims 1 and 12, respectively, and further define the invention defined in Claims 1 and 12, respectively. Thus, for the reasons set forth above and because of the additional inventive features recited in the dependent claims, Applicant respectfully submits that Claims 5-10, 13 and 15 are patentably distinguished over Leon. Applicant respectfully requests the Examiner to withdraw the rejection of Claims 5-10, 13 and 15 and to pass Claims 5-10, 13 and 15 to allowance.

CONCLUSION

Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested.

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If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Respectfully submitted,

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Dated: ~~Oct~~ Nov. 2, 2001

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